REMARKS

Only independent claims 56 and 62, and claims depending therefrom, remain pending. The net effect of the claim amendments is to cancel claims. The amendment should be entered after final.

Claims 34, 39, 45-47, 56, 58 and 62 are currently pending. Claims 56 and 62 are independent.

Claims 32, 41, 42, 57, 59-61, 63 and 64 have been canceled by the present amendment. Applicants make no admission regarding the cancellation of these claims and reserve the right to pursue the subject matter of these claims in this application or in a continuing application.

Claims 34, 39, 45-47 and 58 are currently amended. Each claim is a multiple dependent claim, and the only amendments have been to cancel certain claim dependencies to claims that have been canceled.

Applicant respectfully requests after final entry of the amendment. The amendment places the claims in condition for allowance. In the alternative, the amendment will reduce the number of issues for an appeal, if necessary.

With regard to independent claims 56 and 62, the Office asserts that:

> the [alleged] intended use of the composition "wherein the lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes", does not further limit the claim because the recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Official Action mailed 3 August 2010, page 5.

As discussed herein, the Fahim handwash is not biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes. The Office has asserted that Fahim is biocompatible because of the results of a dermal irritation test and ocular

irritation test in the Examples of Fahim. Even if the handwash of Fahim is biocompatible with the epidermis and eye[1], this does not mean that Fahim is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.

Biocompatible is defined as follows "the condition of being compatible with living tissue or a living system by not being toxic or injurious and not causing immunological rejection." *Merriam-Webster's Medical Dictionary*, 2002.

Use of a lock flush solution in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes necessarily results in a portion of the solution entering into the body of a user by oral or parenteral route and directly contacting the bloodstream and/or internal tissues of a user. Thus, for a lock flush solution to be biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes, such solution must be biocompatible when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues. Biocompatibility with the bloodstream and internal tissues is ***different*** than biocompatibility with external contact with the body. This difference is explained below.

There is a clear difference in the effect a toxin may have when used externally to the body, such as on the skin or the eye, as compared to given direct access into the body, when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues.

Applicants have offered direct declaratory evidence, which is supported by independent research, including research sponsored and adopted by the U.S. government, relating to this key distinction for internal versus external biocompatibility. A declaration was provided by Dr. Stephen Olmstead, an internist, cardiologist and scientist, and Paul Ketteridge, a pharmacist and former drug consultant for the FDA, which recites that:

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[1] Applicants do no acquiesce to any conclusion the Office may have drawn from the tests of Fahim, including that the Fahim handwash is biocompatible for the epidermis and eye.

Skin cleansers and other topical preparations meant for application on epidermal surfaces may employ active agents and excipients that would be toxic if ingested. For this reason, no medical practitioner or person skilled in the art of antimicrobials would ever find that a patent on a skin cleanser would teach anything obvious to the invention of an antimicrobial for oral or parenteral administration. ***An obvious example is that plain chlorine bleach, 3–6% sodium hypochlorite (NaClO), is an excellent antimicrobial. While it is irritating to the skin, contact with dilute solutions can be tolerated. However, ingestion of chlorine bleach is highly toxic causing corrosive tissue damage of the gastrointestinal track.***

Declaration of Olmstead & Ketteridge, paragraph 3 (emphasis added).

With an awareness of this key distinction between the effect of external (skin or eye) contact of a toxin compared to internal contact of a toxin, Dr. Olmstead and Mr. Ketteridge declared that "Fahim teaches compositions comprised of potentially toxic chemicals unsuitable for oral ingestion or parenteral administration." Declaration of Olmstead & Ketteridge, paragraph 3.

Moreover, regarding the individual components of the Fahim handwash -- triclosan, PCMX, and glutaraldehyde --the Office must recognize that each is not biocompatible when given direct access into the body, when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues.

For example, triclosan is not biocompatible when given direct access into the body, when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues:

> The EPA gives triclosan high scores both as a human health risk and as an environmental risk. Triclosan is a chlorophenol, a class of chemicals suspected of causing cancer in humans. Externally, phenols can cause a variety of skin irritations, but since they can temporarily deactivate sensory nerve endings, contact with it may cause little or no pain. ***Taken internally, even in small amounts, phenols [such as triclosan] can lead to cold sweats, circulatory collapse, convulsions,***

coma, and death. Reports suggest that triclosan can combine with chlorine in tap water to form chloroform gas (PMID 15926568), which the EPA classifies as a probable human carcinogen. Triclosan was the subject of a United Kingdom cancer alert. Triclosan reacts with the free chlorine in tap water to produce lesser amounts of other compounds, like 2,4-dichlorophenol (PMID 15926568). Most of these intermediates convert into dioxins upon exposure to UV radiation (from the sun or other sources). Dioxins are extremely toxic and are very potent endocrine disruptors. Triclosan has been shown to disrupt testosterone biosynthesis in testicular Leydig cells (PMID 18655822).

Declaration of Olmstead & Ketteridge, paragraph 4 (emphasis added).

Further, the Office must recognize that PCMX is not biocompatible when given direct access into the body, when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues:

> Fahim teaches 4-chloro-3,5-dimethyl phenol (Chloroxylenol, also known as parachlorometaxylenol, or PCMX) as a component. ***While chloroxylenol is used as an antimicrobial in soaps, shampoos, and sprays, it has never been approved for oral or parenteral administration. Despite its topical use, chloroxylenol may be a skin, eye or respiratory tract irritant and is considered harmful if swallowed.*** … This again underscores that there is nothing in Fahim that makes it relevant to any bactericidal application except topical uses. The PAN Pesticides Database maintained by the Pesticide Action Network North America … notes that Chloroxylenol is highly corrosive and causes caustic eye, skin, mouth and gastrointestinal injuries. Ingestion can result in nausea, vomiting, diarrhea, hypotension, myocardial failure, pulmonary edema, neurological changes, liver and renal toxicity, methemoglobinemia, and hemolysis. It is readily apparent that this component of Fahim cannot be sterilized, placed in a vial, and administered to humans. No reasonable practitioner skilled or even unskilled in the art would even think about doing this.

Declaration of Olmstead & Ketteridge, paragraph 5 (emphasis added).

Moreover, the Office must recognize that glutaraldehyde is not biocompatible when given direct access into the body, when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues. See Declaration of Olmstead & Ketteridge, paragraphs 7-11. In particular, glutaraldehyde has been shown to be highly toxic when allowed to contact the bloodstream. See Declaration of Olmstead & Ketteridge, paragraphs 9-11 (Glutaradehyde has a median lethal dose that places glutaraldehyde as highly toxic according to Occupational Safety and Health Administration).

Thus, understanding that there is a clear difference in the effect a toxin may have when used externally to the body, such as on the skin or the eye, as compared to given direct access into the body, when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues, the Office must consider the above declaratory evidence, which is supported by independent research, including research sponsored and adopted by the U.S. government. The evidence shows that even if the handwash of Fahim is recognized as biocompatible with the epidermis and eye[2], the handwash of Fahim must be considered as not being biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.

The handwash of Fahim is not biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes, at least because the handwash of Fahim is not biocompatible when given direct access into the body when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues, as required when using in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes. If the handwash of Fahim were administered internally into a user to directly come into contact with the bloodstream and internal tissues, the handwash of Fahim would not be compatible internally in the body of a living organism, but would be toxic and injurious and cause immunological rejection.

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[2] Applicants do no acquiesce to any conclusion the Office may have drawn from the tests of Fahim, including that the Fahim handwash is biocompatible for the epidermis and eye .

A composition that is toxic and injurious and causes immunological rejection, as the handwash of Fahim is when administered internally to directly come into contact with the bloodstream and internal tissues, is not biocompatible. A biocompatible composition requires that composition is "compatible with living tissue or a living system by not being toxic or injurious and not causing immunological rejection." *Merriam-Webster's Medical Dictionary*, 2002.

Accordingly, the handwash of Fahim is not biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes. This is the result of a clear structural difference between the handwash of Fahim and the claimed composition. The Office asserts that if the prior art structure is capable of performing the [alleged] intended use, then it meets the claim. Official Action mailed 3 August 2010, page 9. While applicants again stress that "biocompatible" is not an intended use, even if "biocompatible" can be so interpreted, the case law establishes that, if the prior art structure is not capable of performing the [alleged] intended use, then is it does not meet the claim. See In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997); In re Swineheart, 169 USPQ 226 (CCPA 1971); and In re Pearson, 181 USPQ 641 (CCPA 1974).

In fact, the case law is clear that an intended use recitation may establish a patentable distinction if the recitation "define[s], indirectly at least, some characteristic not found in the old composition." In re Pearson, 181 USPQ 641, 644 (CCPA 1974). The claim recitation that the "lock flush composition is biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes," directly, or at least indirectly, establishes some characteristic not found in Fahim (as discussed *supra*).

Further, in the Official Action, the Examiner asserts that "[t]he arguments are not commensurate in scope with instant claims because instant claims do not recite administration of instant compositions orally or parenterally." Official Action mailed 3 August 2010, page 8. However, as established above, the arguments are commensurate in scope with a claim that requires that the lock flush composition be biocompatible for use in in-

dwelling access catheters, urinary catheters, nasal tubes and throat tubes. For a solution to be biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes, such solution must be biocompatible when internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues. The Office has relied upon the information in Fahim related to ***external*** contact (skin and eyes), but not ***internal*** contact (in the bloodstream, orally or parenterally). Applicants have provided the relevant information related to internal contact (internally entering a user orally and/or parenterally to directly come into contact with the bloodstream and internal tissues). Accordingly, Applicants have established that the handwash of Fahim is not biocompatible for use in in-dwelling access catheters, urinary catheters, nasal tubes and throat tubes.

Accordingly, the Office is requested to withdraw the rejection of independent claims 56 and 62, and claims 34, 39, 45-47 and 58 depending therefrom.

Conclusion

Applicants traverse the rejection for at least the reasons discussed above. However, applicants make no admissions from a lack of a response to any of the Office's assertions.

In the event that there are any questions concerning this amendment, or the application in general, the Examiner is respectfully urged to telephone the undersigned attorney so that prosecution of the application may be expedited.

The Director is hereby authorized to charge any appropriate fees under 37 C.F.R. §§ 1.16, 1.17 and 1.20(d) and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 02-4800.

Respectfully submitted,

BUCHANAN INGERSOLL & ROONEY PC

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